FTS-USDA-APHIS

Moderator: Andrea McNally
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1:00 pm CT

Coordinator: Good afternoon everyone. Thank you all for standing by and welcome to today's conference call. At this time all lines are on listen only during today's conference.

During the question and answer session of the call you will be prompted to press star 1 on your touchtone phone and you will need to record your name so you may be introduced to ask your question.

Today's conference is also being recorded and if you have any objections you may disconnect at this time. I will now turn our conference over to Miss. Andrea McNally. Ma'am, you may begin.

Andrea McNally: Hi everyone. Thanks for joining us. This is Andrea McNally with APHIS Public Affairs. We're going to begin with a few short remarks and then we'll move to a question and answer period. (Cindy).

Cindy Smith: Hello I'm Cindy Smith, Administrator of USDA's Animal and Plant Health Inspections Service. It wasn't that long ago, however, that I was head of the agency's Biotechnology Regulatory Services Program.

I continue to have a deep interest in the oversight and introduction of genetically engineered or GE organisms. Therefore, I'm pleased to be a part of today's announcement which details the development of the agency's new Biotechnology Quality Management System or BQMS which we plan to implement in partnership with our sister agency, the Agricultural Marketing Service.

To protect plant health in the United States it's essential that applicants that receive our approval to import, move and field test genetically engineered organisms comply with all APHIS regulations and permit conditions.

We currently ensure compliance with our GE regulations through targeted inspections conducted at critical stages and we apply consistent and appropriate enforcement actions. We also require those conducting field tests to identify and self-report any potential noncompliance incidence and many developers have compliance reporting programs.

What we found, however, is that some companies and researchers could benefit from additional assistance to develop the infrastructure, processes, and documented quality controls and procedures necessary to achieve compliance.

We had that expertise here at USDA and BQMS will be a compliance assistance program to help interested parties develop appropriate planning and oversight practices for field trials and movements of GE organisms in accordance to our regulations.

BQMS will be voluntary and when fully implemented will complement our existing compliance efforts and increase our oversight of GE organisms.

Companies and researchers who receive APHIS approval to introduce GE organisms will benefit from participating in BQMS because the program will help to ensure they have best management practices in place to effectively meet all regulatory requirements.

We support the effort of companies and researchers who are serious about achieving regulatory compliance and we plan to publicly recognize BQMS participants. Voluntary participation in the BQMS program will demonstrate to APHIS and the public that these participants are committed to meeting the requirements for introducing GE organisms.

BQMS is being designed to support all applicants from universities and small businesses to large companies and corporations that receive approval to field test or move regulated GE organisms.

BQMS will not replace risk assessments or inspections. I want to assure that everyone that the current authorization process will still be used to place specific requirements on notification and permit holders such as the requirement to identify and self-report any potential noncompliance incidents and APHIS will continue to conduct inspections to ensure compliance with regulations.

Participating in the BQMS is simply one more step that companies and researchers can take to ensure effective management and quality compliance.

I anticipate that we will begin implementing BQMS in spring of 2008. And I encourage participation from all applicants who seek approval from APHIS to introduce GE organisms.

I would now like to introduce Rebecca Bech, Deputy Administrator for Biotechnology Regulatory Services who will provide details on how BQMS will be structured. In addition we have Jim Riva, Chief of the Agricultural Marketing Services Audit Review and Compliance branch with us as well. Rebecca?

Rebecca Bech: Yes, good afternoon and thank you for joining us on the phone today. As Cindy just mentioned I'm Rebecca Bech Deputy Administrator for Biotechnology Regulatory Services. And we're very happy to be making this announcement today so I'd like to take the opportunity to go into a little bit more detail about how BQMS will be organized and implemented.

Through BQMS we will better support companies and researchers efforts to comply with all of APHIS's regulatory requirements and permit conditions. The goal of BQMS is to help participants analyze their operations, identify control points where problems could occur and apply mitigation measures to address those vulnerabilities.

In addition, BQMS will help us to head off compliance problems before they occur. The focus then will be on prevention rather than reacting once a compliance infraction has already happened.

We recognize that the Biotechnology Industry Organization already has a quality management program in place called Excellence Through Stewardship. This initiative is industries program on quality management to ensure product integrity of biotech derived plant products throughout the product life cycle.

While our program, BQMS, is focused on the quality of the process for safely introducing these GE organisms and field trials. We applaud Bios efforts and

believe BQMS will complement the work that has already been done by the industry.

Among other things, BQMS will offer guidance, education, and outreach as well as verification services to confirm that participants have required BQMS procedures in place and that they are performed correctly.

BQMS will incorporate industries best management practices and the principals established by national and international standard sitting bodies such as the Codex's Alimentarius Commissions and the International Organization for Standardization.

In order to accommodate a wide range of companies and researchers and address the specific needs we envisioned two different program levels for BQMS participants.

The first we're calling Level A will be geared towards participants that do not have formal management systems in place. These are participants such as small businesses and universities and it will help them then develop effective management procedures.

Level B is intended for those participants that grow GE plants at multiple sites often through the use of cooperators and they already have existing formal management systems in place.

Level B will emphasize training guidelines and documentation procedures to ensure accountability at all levels by all involved parties. When finalized the requirements then for each level will be thoroughly explained to industry so that companies and researchers can determine the right level for them. APHIS

intends to oversee the BQMS in partnership with AMS as Cindy just mentioned.

APHIS will provide participants with guidance and assistance to develop and document BQMS best management practices and AMS will manage the audit program in accordance with the International Organization for Standardization Guidelines and accredited third-party auditors.

AMS performs similar functions for other audit-based quality verification systems in operation throughout USDA. APHIS will continue to require those conducting field tests to identify and self-report any potential noncompliance incidents and will still conduct inspections to ensure that regulated entities are complying with our all of our requirements.

The frequency and thoroughness of the inspections will not change. So the purpose of BQMS then is to complement our current practices. BQMS will be used to target planning and management practices that may affect a participant's ability to meet the regulatory requirements.

As part of the program's emphasis on preventative measures, participants will be encouraged to correct any deficiencies discovered in the BQMS audit before the problems develop.

So we're excited formalizing this initiative and making it available. We will use our knowledge and our experience as well as stakeholder input in the latest scientific information to implement BQMS.

In the coming months we will be holding meetings to provide industry, academia and other interest groups the opportunity to contribute their input

concerning the scope of the BQMS, the audit verification criteria and incentive plans to attract program for participants.

We will post meeting information on our website and reach out to these groups to encourage participation in the development process.

So I like to thank you for calling and today and (Jim) and I are available to answer any questions that you have.

Andrea McNally: (Jill) before we open up the floor to questions I want to give some guidelines for how those questions will be handled.

The first guideline is that we want to remind everyone that this call is for reporters only. Questions from stakeholders will be answered in a different forum. This call is also specific to BQMS related questions. Reporters that have unrelated questions about biotechnology can contact me, Andrea McNally at 202-690-4178 after this call.

Also please limit yourself to one question so that we can get to as many as possible and if you could state your name and affiliation that would be helpful. I think we're ready now.

Coordinator: Thank you. At this time please press star 1 and record your name when prompted to ask your question. Once again please press star 1 and record your name when prompted to ask your question.

One moment please, for the first question.

Our first question comes from Elizabeth Weise with USA Today. Ma'am, your line is open.

(Elizabeth Weiss): Thanks for taking my call. Why was the decision made to make this a voluntary system rather than a required system?

Rebecca Bech: Well, APHIS understands that implementing the quality management program requires resources and it will have associated costs. So BQMS will be a voluntary program to ensure that there's no undue burden placed on small businesses or researchers that might not have the resources available to implement the BQMS requirements.

Also BQMS will be a service to the participants and the regulated entities often seek our advice and information from us on how to meet regulatory requirements. So voluntary participation in the program will demonstrate that participant then is committed to meeting these requirements for the field testing of GE organisms and we believe that we're working on incentives that will encourage anticipation. We are still determining what those are but we believe these incentives will attract program participants.

And in addition we believe one of the other benefits for Level B program participants that BQMS will prepare them for then the International Organization for Standardization or what they call ISO Certification and these organizations may also then apply for certification if they choose. And that's a highly recognized international certification process.

Coordinator: Thank you. Our next question comes from (Jackie) and I believe she said her name was Fatka. I apologize if that is incorrect. Please state your company before asking your question.

Jackie Fatka: Hello this is Jackie Fatka from Feedstuffs. Can you elaborate a little bit more on how this appears together with the Bios Excellence Through Stewardship

Program and also is this related at all to the court ruling given earlier this year about the biotech alfalfa and regulation and environmental impact studies and so forth?

Rebecca Bech: BIO's program Excellence Through Stewardship Program is founded on a quality management system and best management practices. And we've certainly from a very early point have discussed with industry the use of best management practices and have encouraged that. And so we ourselves then have been looking at how to incorporate best management practices and providing incentives for those researchers that are actually doing the best management practices programs. And Bio has formalized that program.

They are currently working on details for the program as we are so we're working closely with Bio as well other interested stakeholders in developing the process. We see it as being complementary to their program and we encourage the use of the program.

Coordinator: Thank you. Our next question comes from (Stewart Doane). Please announce your company before asking your question.

(Stewart Doane): Sure. (Stewart Doane), Clear Channel Action Networks in Little Rock. Thanks for the call. I'm wondering if this program is in any way a byproduct of the USDA's Liberty Link Rice Investigation?

Also how can this program strengthen USDA's hand in helping importer countries feel more comfortable with our biotech products?

Rebecca Bech: Okay. Well past compliance incidents including the Rice incident were taken into consideration while we developed - while we are begin developing the BQMS framework. However, another major consideration was what more

could we do to ensure companies and researchers that have best management practices in place to meet the requirements as we've seen the number of field tests and the movement permits have increase. And the complexity of the request that we've been getting have increased.

So we've actually been talking about the best management practices for some time. When we first put our compliance division in place we had a strategy where we wanted to focus on prevention measures. And we've been working toward that end now for several years.

Your second part of the question about the international and export components. We do believe that having best management practices in place and participating in a program such as this will give more confidence to other countries as they look at how field testing is done here in the U.S.

Andrea McNally: And Carol before we get to the next question I just want to remind everyone that we need to limit ourselves to one question per reporter.

Coordinator: Thank you. We have one more question at this time. I just liked remind parties to please press star 1 and to record the name if they will like to ask a question.

Our last question at this time comes from Ms. (Baben). She is with Marketplace. Ma'am, please pronounce your first name before asking your question?

(Janet Baben): Yes. Hi, this is (Janet Baben) with Marketplace. In light of the fact that there are no other questions, I'm going to ask two questions. But my first question is most important.

First off will BQMS allow APHIS to conduct a more detailed review of applications for plant experimental plots of GE crops in any way? And my second question if there's time. Are there any - are any of the guidelines of BQMS will be using, are any of them new? Thank you.

Rebecca Bech: It's important to note that the BQMS is focused on a management systems approach and is not permit specific.

What we're looking at is management systems that the applicants have in place and how they managed the many field trials or and the research that they have for the field trials. So it's not a specific permit. We do intend to continue our very thorough review of the permits that we get and that process will not change.

Coordinator: We do have one more question that just came in from (Christopher Daring) with Reuters. Sir, your mind is open.

(Christopher Daring): Thank you. I just want to find out a little bit more. Does this at all relate to the proposal or general guidelines, I guess, that you folks issued in July and how you were looking to overhaul the GMO Regulations? Is this at all part of that or if not what is the current, you know, track of what you talked about in July?

Rebecca Bech: Well, I believe what you're referring to is our draft Environmental Impact Statement.

(Christopher Daring): Right.

Rebecca Bech: That we put out that recently the comment period just closed. This is a separate initiative, however, we are looking at our regulations and the draft

Environmental Statement will provide valuable input into how we will be revising those regulations in the future.

(Christopher Daring): Thank you.

Coordinator: Once again, if you like to ask a question please press star 1 and record your name at this time.

Andrea McNally: So if there are no more questions, I guess we will conclude the technical briefing.

Coordinator: We have no more questions at this time, ladies.

Andrea McNally: Okay. Thank you all for joining us.

Coordinator: That does conclude today's conference call. Thank you all for participating and have a great afternoon.

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